UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,995	08/07/2007	Venkata-Rangarao Kanikanti	AH/Le A 36 780	4575
71285 BAYER HEAL	7590 08/03/201 THCARE LLC	EXAMINER		
P.O.BOX 390		YEAGER, RAYMOND P		
SHAWNEE MISSION, KS 66201			ART UNIT	PAPER NUMBER
			1651	
			NOTIFICATION DATE	DELIVERY MODE
			08/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

janis.wright.b@bayer.com jessica.monachello.b@bayer.com andrea.ewell.b@bayer.com

	Application No.	Applicant(s)				
Office Action Comments	10/559,995	KANIKANTI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Raymond P. Yeager	1651				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Responsive to communication(s) filed on <u>26 A</u>	pril 2010					
	· · · · · · · · · · · · · · · · · · ·					
<u></u>	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
closed in accordance with the practice under Lx parte Quayle, 1930 C.D. 11, 400 C.C. 210.						
Disposition of Claims						
4)⊠ Claim(s) <u>1-3</u> is/are pending in the application.	☑ Claim(s) <u>1-3</u> is/are pending in the application.					
4a) Of the above claim(s) 2 is/are withdrawn fr	4a) Of the above claim(s) <u>2</u> is/are withdrawn from consideration.					
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>1 and 3</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/o	or election requirement.					
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
	12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).					
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
application from the International Bureau (PCT Rule 17.2(a)).						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	nte				
3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 5) Notice of Informal Patent Application Other:						

Application/Control Number: 10/559,995 Page 2

Art Unit: 1651

DETAILED ACTION

Applicant's arguments filed 04/26/2010 have been fully considered. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

- Claims 1 to 3 are pending;
- Claim 1 has been amended;
- Claim 2 has been withdrawn;
- Claim 3 is new;
- Claims 1 and 3 are under consideration.

REJECTION/OBJECTION STATUS

Rejections/Objections Maintained

Note - Specification

Applicant's arguments have been fully considered but they are not persuasive. The use of the trademarks has been noted within this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

• Claim Rejections – 35 USC § 103

O Applicant's arguments have been fully considered but they are not persuasive. Claim 1 and new claim 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,004,582 (Publication date: 12/21/1999; as cited in the 11/27/2009 office action), hereafter referred to as the Faour patent, in view of US patent application publication 2003/0175326 (Publication date: 09/18/2003; Filing date: 08/06/2002; as cited in the 11/27/2009 office action), hereafter referred to as the Thrombe publication, Gennaro, 1990 (Remington's Pharmaceutical Sciences, Chapter 89. Oral Solid Dosage Forms, pp. 1633-1665; as provided in the 11/27/2009 office action), and Federal Registry, 1997 (vol. 62(139) 38906-38907; as provided in the 11/27/2009 office action),

hereafter referred to as FR 1997, as modified by Federal Registry, 1997 (vol. 64(171) 48295), hereafter referred to FR 1999.

Page 3

Applicant has added new claim 3 to further comprise maize starch, povidone, colloidal silicon dioxide, and magnesium stearate. Thus, this rejection is amended as necessitated by amendment.

REJECTION REVISED

Applicant claims a tablet comprising approximately 20 to 45 percent enrofloxacin, 18 to 35 percent lactose, microcrystalline cellulose, and 5 to 20 percent meat flavor. The claims further recite 5 to 10 percent maize starch, 1.5 to 4 percent polyvinyl pyrrolidone, 0.05 to 0.3 percent colloidal silicon dioxide, and 0.4 to 1 percent magnesium stearate.

The Faour publication teaches a formulation comprising a therapeutic agent in a tablet (column 4:63-66 and column 5:65 to column 6:10) and comprises microcrystalline cellulose and lactose (column 7:38-49; column 9:38-52; column 10:58-67; and column 11:34-46) and provides a working example comprising a therapeutic agent, lactose, and microcrystalline cellulose (columns 18-19, examples 2). The Faour patent notes that a number of agents, such as antibacterial agents, are equivalents for formulation and recite enrofloxacin as one of the antibacterial substances (column 13:53 to column Since the therapeutic agents and enrofloxacin are considered equivalent therapeutic agents for formulation purposes in the Faour patent, it would have been obvious to one of ordinary skill in the art to provide a tablet formulation comprising enrofloxacin, lactose, and microcrystalline cellulose (limitations in instant claim 1). The Faour patent also provides for the addition of flavoring to the formulation (column 11:58 to column 12:11) and recites that the therapeutic agent is present at 0.1 to 99 percent of the formulation (column 9:28-37) and thus it would be obvious to one of ordinary skill in the art to optimize the therapeutic agent concentration per MPEP § 2144.05.II. The Faour patent teaches the active agent can be present at 0.1 to 99.9 percent weight in the core, about 9 to about 45 percent microcrystalline cellulose, about 42 percent lactose (column 9:28-37; column 15:60 to column 19:41; and column 20:7-24), about 10 percent maize starch, povidone, about 0.3 percent colloidal silicon dioxide, and about 1

percent magnesium stearate (column 9:28-37; and columns 18-20, example 2). As the Faour patent teaches a tablet prior to coating, it would be obvious to one of ordinary skill in the art that this compressed granular formulation is appropriate for tablets which are uncoated.

The Faour patent does not expressly teach meat flavoring or the claimed concentrations of lactose (18 to 35 percent) and meat flavour (5 to 20 percent). This deficiency is cured by the teachings of the Thrombe publication and Gennaro, 1990 and FR 1997 as modified by FR 1999. The 'Thrombe publication teaches the use of antibacterial therapeutics and antibiotics in tablet form for veterinary treatment and FR 1997 as modified by FR 1999 teaches enrofloxacin (BAYTRIL®) tablets for administration to canines (FR 1997, 38906, column 2 to page 38907, column 1 as modified by FR 1999, page 48295, columns 1-2) thus it would be obvious to one of ordinary skill in the art to provide a tablet formulation for canines comprising enrofloxacin, especially as the Thrombe publication teaches the incorporation of beef flavor into the tablets to improve voluntary acceptance by canines (noted below). The '326 publication teaches a palatable tablet (paragraphs 13 and 18). The Thrombe publication teaches the drug is present at 5 to 95 percent of the formulation (paragraph 173), and 1 to 30 percent of a palatability improving agent (paragraph 179). Further, the Thrombe publication provides working examples of formulations preferred by canines comprising 1, 5, and 10 percent artificial beef flavor (example 1, table 1, paragraphs 108-110). Gennaro, 1990 teaches that both lactose and microcrystalline cellulose are diluents used in tablet formulation and further disclose that 5 to 15 percent of microcrystalline cellulose is used as an excipient in direct compression formulas (page 1635, column 1, tablet ingredients to column 2, paragraph 4). Gennaro, 1990 also teaches direct compression wherein lactose in incorporated as a vehicle and provides working examples wherein lactose is present at about 10 to about 50 percent (page 1645, column 1, direct compression to page 1646, paragraph 4 and pages 1654-1656, working examples). Thus it would have been obvious to one of ordinary skill in the art to optimize the concentrations of ingredients per MPEP § 2144.05.II. Further, Gennaro teaches povidone and polyethylene glycol are functionally equivalent binders in tablet

formulation (page 1635-1636, Binders) and as such the presence of polyethylene glycol in the formulation in the Faour patent is a functional equivalent to povidone. As such it would be obvious to one of ordinary skill in the art to use only povidone rather than povidone and polyethylene glycol in the formulation as the two are considered functional equivalents. As such, these components are the exact same components as recited in instant claim 3.

Page 5

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a tablet comprising enrofloxacin, lactose, microcrystalline cellulose, maize starch, povidone, colloidal silicon dioxide, magnesium stearate, and flavoring agent as taught by the Faour patent and provide artificial beef flavor (i.e. meat flavor) as the flavoring agent as taught in the Thrombe publication and optimize the ingredients as taught by the Thrombe publication and Gennaro, 1990. One of ordinary skill in the art would have been motivated to do this because the '326 publication teaches palatability improving agents such as artificial beef flavor increase the voluntary acceptance by canines (paragraphs 108-110, and table 1), FR 1997 as modified by FR 1999 teaches enrofloxacin tablet for administration to dogs for management of diseases associated with bacteria susceptible to enrofloxacin (FR 1997, column 2, 580.812 item (2)), and Gennaro, 1990 teaches diluents such as lactose and microcrystalline cellulose affect the stability of the formulation (page 1635, column 1, paragraphs 2-4 and column 2, paragraph 3) and as such are considered result-effective variables which may be optimized per MPEP § 2144.05.II. In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

RESPONSE TO APPLICANT'S ARGUMENTS

Application/Control Number: 10/559,995

Art Unit: 1651

• Applicant argues both the Faour patent and the Thrombe publication teach away from an uncoated tablet. The MPEP § 2141.02. VI. notes "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." [In re Fulton, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). >See also MPEP § 2123.] The Faour patent is drawn to coated tablets but teaches granulated formulations which may be compressed and then coated, as discussed above. As such, the Faour patent teaches a tablet prior to coating, it would be obvious to one of ordinary skill in the art that this compressed granular formulation is appropriate for tablets which are uncoated. Further, the Thrombe publication discloses uncoated tablets (figures 2 and 4) which differ in their dissolution properties. As applicant has not claimed a difference in the dissolution parameter the disclosed uncoated tablets render obvious the instant claims.

Page 6

Applicant asserts the combination of the Faour patent, the Thrombe publication, and the Federal Registry would teach a coated tablet with lactose and microcrystalline cellulose resulting in a tablet different from the present invention. Applicant fails to advance any specific reasons or evidence, aside from Counsel's own allegation, in support of this position that the combination of references would result in a different invention. This assertion by Counsel is an unsupported allegation and fails to take the place of evidence in the record. Statements of this nature are clearly unpersuasive in accordance with the guidance provided at MPEP 2145, which states "The arguments of counsel cannot take the place of evidence in the record." Further, as discussed above, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a tablet comprising enrofloxacin, lactose, microcrystalline cellulose, maize starch, povidone, colloidal silicon dioxide, magnesium stearate, and flavoring agent as taught by the Faour patent and provide artificial beef flavor as the flavoring agent as taught in the Thrombe publication and optimize the ingredients as taught by the Thrombe publication and Gennaro, 1990 because the '326 publication teaches palatability improving agents such as artificial beef flavor increase the voluntary acceptance by canines, FR 1997 as modified by FR 1999 teaches

Application/Control Number: 10/559,995

Art Unit: 1651

enrofloxacin tablet for administration to dogs for management of diseases associated with bacteria susceptible to enrofloxacin, and Gennaro, 1990 teaches the excipients affect the stability of the formulation and are optimizable.

- Applicant asserts meat flavoring type substances impair the mechanical properties of a tablet which must be overcome by optimizing the ingredients and concentrations. Once again, applicant fails to advance any specific reasons or evidence, aside from Counsel's own allegation, in support of this position that flavoring impairs the mechanical properties. This assertion by Counsel is an unsupported allegation and fails to take the place of evidence in the record. See MPEP 2145. Further, as discussed supra, the combination of excipients affect the stability of the formulation and are optimizable (as noted by applicant when stating "the choice of optimal ingredients as well as the choice of each ingredient's concentration is important").
- Applicant argues the instantly claimed invention has unexpected mechanical properties as evidenced by Dr. Kanikanti's declaration. The declaration under 37 CFR 1.132 filed 04/26/2010 is insufficient to overcome the rejection of claim 1 (or new claim 3) based upon the 35 USC 103 rejection as set forth in the last Office action because: The batch designation is unclear, the batches are not commensurate in scope with the claims, and based on Lewis et al, 1999 (Pharmaceutical Experimental Design, Chapter 9. Mixtures. Pp.394, 395) the results are not unexpected as discussed herein. First it is unclear which batch is considered applicant's as the applicant's arguments recite batch 1164 is the present invention and the declaration recites batch 1165 is the present invention. Regardless, with new evidence presented, the examiner must determine based on the knowledge of one of ordinary skill at the time the invention was made if such results are considered unexpected. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., percentage of maize starch, povidone, and colloidal silicon dioxide) do not appear to be recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition the neither the 1164 nor the 1165 batch

appear to be commensurate with the claims regarding the concentration of maize starch, povidone, and colloidal silicon dioxide. Lastly, the results are not unexpected as Lewis et al, 1999 reports that increased lactose concentrations improves hardness and slightly increases friability whereas increased starch concentrations results in lower friability (pp. 394, 396). Further, Lewis et al, 1999 reports that adding a small amount of microcrystalline cellulose improves friability (pp. 394, 396).

NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT Claim Rejections - 35 USC § 103

• Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,980,914 (Publication Date: 11/09/1999), hereafter referred to as the Gerolymatos patent, in view of US Patent 6,004,582 (Publication date: 12/21/1999; as cited in the 11/27/2009 office action), hereafter referred to as the Faour patent, US patent application publication 2003/0175326 (Publication date: 09/18/2003; Filing date: 08/06/2002; as cited in the 11/27/2009 office action), hereafter referred to as the Thrombe publication, Gennaro, 1990 (Remington's Pharmaceutical Sciences, Chapter 89. Oral Solid Dosage Forms, pp. 1633-1665; as provided in the 11/27/2009 office action), and Federal Registry, 1997 (vol. 62(139) 38906-38907; as provided in the 11/27/2009 office action), hereafter referred to as FR 1997, as modified by Federal Registry, 1997 (vol. 64(171) 48295), hereafter referred to FR 1999.

Applicant has added new claim 3 to further comprise maize starch, povidone, colloidal silicon dioxide, and magnesium stearate. Thus, this new grounds of rejection is necessitated by amendment.

NEW REJECTION AS NECESSITATED BY AMENDMENT

Applicant claims a tablet comprising approximately 20 to 45 percent enrofloxacin, 18 to 35 percent lactose, microcrystalline cellulose, and 5 to 20 percent meat flavor. The claims further recite 5 to 10 percent maize starch, 1.5 to 4 percent polyvinyl pyrrolidone, 0.05 to 0.3 percent colloidal silicon dioxide, and 0.4 to 1 percent magnesium stearate.

The Gerolymatos patent teaches an uncoated tablet formulation comprising an antimicrobial therapeutic with functionally equivalent excipients including a binder such as microcrystalline cellulose, povidone, starch and/or lactose, a disintegrating agent such as maize starch, a lubricant such as magnesium stearate, a glidant such as colloidal silicon dioxide, and a sweetening or flavoring agent (column 7:20-43; and column 8:1-3). Though instant claim 3 provides "consisting of" language, the excipients recited are considered functional equivalents as note where the Gerolymatos patent recites functions for the given excipients.

The Gerolymatos patent do not expressly teach the percentages of each compound or a meat flavoring or the claimed concentrations of lactose (18 to 35 percent) and meat flavour (5 to 20 percent) present but this deficiency is cured by the teachings of the Faour patent, the Thrombe publication and Gennaro, 1990 and FR 1997 as modified by FR 1999.

The Faour patent teaches a granulation composition for tableting (columns 5-7 and 9-11) comprising 0.1 to 99 percent an active agent, about 40 percent lactose, about 40 percent microcrystalline cellulose, about 10 percent maize starch, povidone, about 0.3 percent colloidal silicon dioxide, and about 1 percent magnesium stearate (column 9:28-37; and columns 18-20, examples 2-3). The '582 patent notes that a number of agents, such as antibacterial agents, are functional equivalents for formulation and recite enrofloxacin as one of the antimicrobial substances ('582, column 13:53 to column 14:14) and the Faour patent provides. The Thrombe patent teaches the use of antibacterial therapeutics and antibiotics in a tablet form for veterinary treatment and FR 1997 as modified by FR 1999 teaches enrofloxacin (BAYTRIL®) tablets for administration to canines (FR 1997, 38906, column 2 to page 38907, column 1 as modified by FR 1999, page 48295, columns 1-2) thus it would be obvious to one of ordinary skill in the art to provide a tablet formulation for canines containing enrofloxacin, especially as the Thrombe publication teaches the incorporation of beef flavor into the tablets to improve voluntary acceptance by canines (noted below). The Thrombe publication teaches a palatable tablet comprising a 5 to 95 percent active ingredient and 1 to 30 percent of a palatability improving agent (page 2, paragraphs 13

Page 10

Art Unit: 1651

and 18; page 16, paragraph 173; and pages 16-17, paragraph 179). Further, the Thrombe publication provide working examples of formulations preferred by canines comprising 1, 5, and 10 percent artificial beef flavor (page 9, example 1, table 1, paragraphs 108-110). Gennaro, 1990 teaches that both lactose and microcrystalline cellulose are diluents used in tablet formulation and further disclose that 5 to 15 percent of microcrystalline cellulose is used as an excipient in direct compression formulas (page 1635, column 1, tablet ingredients to column 2, paragraph 4). Gennaro, 1990 also teaches direct compression wherein lactose in incorporated as a vehicle and provides working examples wherein lactose is present at about 10 to about 50 percent (page 1645, column 1, direct compression to page 1646, paragraph 4 and pages 1654-1656, working examples). Further, Gennaro teaches povidone and polyethylene glycol are functionally equivalent binders in tablet formulation (page 1635-1636, Binders) and as such the presence of polyethylene glycol in the formulation in the Faour patent is a functional equivalent to povidone. Thus it would have been obvious to one of ordinary skill in the art to optimize the concentrations of ingredients per MPEP § 2144.05.II. As the active ingredient is considered variable and the other ingredients are excipients it would be obvious to one of ordinary skill in the art to optimize the concentrations of therapeutic agent and excipients (such as lactose, povidone, and microcrystalline cellulose) per MPEP § 2144.05.II in light of the Faour patent, the Thrombe publication, and Gennaro, 1990.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide an uncoated tablet comprising excipients as taught by the Gerolymatos patent with the active ingredient enrofloxacin and excipients at concentration as suggested by the tablet before coating in the Faour patent and the Thrombe publication in light of Gennaro, 1990, and provide a meat flavor as taught by the Thrombe publication. One of ordinary skill in the art would have been motivated to do this because the Gerolymatos patent present appropriate pharmaceutical carriers for tableting antibiotics (section 5.2), the Faour patent teaches an appropriate tableting composition for controlling the release of the active ingredient (abstract; column 1:4-10; and column 6:13-15), the Thrombe publication teaches palatability improving agents

Page 11

Art Unit: 1651

such as artificial beef flavor increase the voluntary acceptance by canines ("326, page 9, paragraphs 108-110, and table 1), FR 1997 as modified by FR 1999 teaches enrofloxacin tablet for administration to dogs for management of diseases associated with bacteria susceptible to enrofloxacin (FR 1997, column 2, 580.812 item (2)), and Gennaro, 1990 teaches diluents such as lactose and microcrystalline cellulose affect the stability of the formulation (page 1635, column 1, paragraphs 2-4 and column 2, paragraph 3) and as such are considered result-effective variables which may be optimized per MPEP § 2144.05.II. In light of the forgoing discussion, it would be obvious to one of ordinary skill in the art that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

All claims are rejected; no claims are allowed.

THIS ACTION IS MADE FINAL AS NECESSITATED BY AMENDMENT. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Application/Control Number: 10/559,995 Page 12

Art Unit: 1651

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Thurs 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

/Leon B Lankford/ Primary Examiner, Art Unit 1651